Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

Henry D. Coleman Coleman Sudol Sapone P.C. 714 Colorado Ave. Bridgeport, CT 06605-1601 In Re: Patent Term Extension
Application for
U.S. Patent No. 5,711,958

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NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,711,958, which claims the medical device REPEL-CV, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within <u>one month</u> of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 9, 2010 (75 Fed. Reg. 54887), would be 2,395 days. Under 35 U.S.C. § 156(c):

Period of Extension = RRP - PGRRP - DD - $\frac{1}{2}$ (TP - PGTP)¹ = 4,023 - 0 - 0 - $\frac{1}{2}$ (3,256 - 0) = 2,395 days (6.6 years)

Since the regulatory review period began March 3, 1998, after the patent issued (January 27, 1998), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:

5,711,958

Granted:

January 27, 1998

Original Expiration Date²:

July 11, 2016

Applicant:

Daniel Cohn et al.

Owner of Record:

SyntheMed, Inc.

Title:

Methods for Reducing or Eliminating Post-Surgical

Adhesion Formation

Product Trade Name:

REPEL-CV

Term Extended:

5 years

Expiration Date of Extension:

July 11, 2021

²Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail:

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By FAX:

(571) 273-7755

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Til

Senior Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner for Patent Examination Policy

cc:

Office of Regulatory Policy

Food and Drug Administration

10903 New Hampshire Ave., Bldg. 51, Rm. 6222

Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: REPEL-CV

Docket No.: FDA-2009-E-0414